

LABORATORY QUALITY ASSURANCE EVALUATION PROGRAM

Information Collection Request: # 2067.01

Supporting Statement

**U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Ground Water and Drinking Water**

March 2002

Table of Contents

1. Identification of the Information Collection	4
1(a) Title of the Information Collection	4
1(b) Short Characterization	4
2. Need For and Use of the Collection	5
2(a) Need/Authority for the Collection	5
2(b) Practical Utility/Users of the Data	5
3. Non-duplication, Consultations, and Other Collection Criteria	5
3(a) Non-duplication	5
3(b) Public Notice Required Prior to ICR Submission to OMB	5
3(c) Consultations	6
3(d) Effects of Less Frequent Collections	6
3(e) General Guidelines	6
3(f) Confidentiality	6
4. The Respondents and the Information Requested	6
4(a) Respondents/SIC Codes	6
4(b) Information Requested	6
5. The Information Collected - Agency Activities, Collection Methodology, and Information Management	7
5(a) Agency Activities	7
5(b) Collection Methodology and Management	8
5(c) Small Entity Flexibility	8
5(d) Collection Schedule	8
6. Estimating the Burden and Cost of the Collection	8
6(a) Estimating Respondent Burden	8
6(b) Estimating Respondent Costs	10
6(c) Estimating Agency Burden and Costs	12
6(d) Estimating the Respondent Universe and Total Burden and Costs	14
6(e) Bottom Line Burden Hours and Cost Tables	14
6(f) Reasons for Change in Burden	14
6(g) Burden Statement	14

APPENDIX A

Federal Register Notice: A-1

APPENDIX B

Respondent Burden Tables B-1

APPENDIX C

Agency Burden Tables C-1

APPENDIX D

Total Respondent and Agency Burden Tables D-1

Information Collection Request
Section 1: Part A of the Supporting Statement

1. Identification of the Information Collection

1(a) Title of the Information Collection

EPA Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act

OMB Number: 2040 - NEW

U.S. EPA Tracking Number: 2067.01

1(b) Short Characterization

The U.S. Environmental Protection Agency (EPA) is proposing a Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act (Laboratory QA Program). This voluntary program applies to public and private laboratories that analyze water samples for *Cryptosporidium*. The program will help ensure that laboratories meet the quality assurance and quality control criteria of EPA Method 1622 and EPA Method 1623 (EPA, 2001a, 2001b) when using these methods for the determination of the identity and concentration of *Cryptosporidium* in source water by filtration, immunomagnetic separation (IMS), and immunofluorescence assay (FA) microscopy.. In addition, the program will assist in determining capacity at laboratories to support monitoring under the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR).

Information collection activities required under the Lab QA Program include: a laboratory participation application; initial performance testing (IPT) results; an on-site evaluation of laboratory performance and data quality; and ongoing performance testing (OPT) results. All materials are being collected by the Office of Ground Water and Drinking Water (OGWDW). This information collection will provide EPA with data to verify that the laboratories are capable of producing reliable data from the analysis of *Cryptosporidium* using EPA Method 1622 and EPA Method 1623.

The information collection will involve approximately 60 laboratories (20 laboratories per year) at a total cost of approximately \$236,980, or 4347 labor hours annually. The estimated total Agency burden, including contractual costs, is estimated at \$71,210, or 3399 labor hours annually (Appendix D).

2. Need For and Use of the Collection

2(a) Need/Authority for the Collection

The information collection is needed by EPA to support the *Cryptosporidium* data gathering activities that will be required under the LT2ESWTR. The Laboratory QA Program is being proposed in advance of the LT2ESWTR because the *Cryptosporidium* laboratory evaluation program must be in place and operational before the implementation of the LT2ESWTR. In addition, EPA plans to propose under the LT2ESWTR that drinking water plants monitoring their source waters for *Cryptosporidium* prior to rule implementation may apply to have these data “grandfathered.” Implementing the Laboratory QA Program as soon as possible will help ensure that qualified laboratories are available to drinking water plants that are interested in pursuing this option.

2(b) Practical Utility/Users of the Data

Information collected under the Laboratory QA Program will be used by EPA to verify that *Cryptosporidium* occurrence data are generated by qualified laboratories that can perform the analyses acceptably. Use of qualified laboratories for source water monitoring by drinking water utilities will help ensure that the data collected are of known and reliable quality. Data quality could potentially be compromised in the absence of a program such as the Laboratory QA Program.

A list of laboratories meeting the evaluation program criteria will be made available to the public and will provide a resource to aid drinking water utilities (and others interested in monitoring water for *Cryptosporidium* occurrence for the protection of public health) in selecting a qualified analytical laboratory. Successful participation in the voluntary Laboratory QA Program also will qualify laboratories to analyze samples for *Cryptosporidium* monitoring programs requiring sample analyses only by qualified laboratories.

3. Non-duplication, Consultations, and Other Collection Criteria

3(a) Non-duplication

The information requested from the respondents under this ICR is not available from other sources. The information requested will be used to assess the current ability of a laboratory to reliably analyze *Cryptosporidium* in water using EPA Method 1622 and EPA Method 1623. Information submitted for previous programs, such as the Information Collection Rule, would not be applicable because older analytical methods were used and quality control requirements were different. The determination that this information by collected is not available from other sources was made by the Office of Ground Water and Drinking Water Technical Support Center (TSC), who will be administering the Laboratory QA Program, and TSC’s contractors, both of which have worked closely since 1996 with the limited community of capable laboratories that will be affected by this

information collection.

3(b) Public Notice Required Prior to ICR Submission to OMB

A copy of the Federal Register (67 FR 9731, March 4, 2002) notice which announces EPA's proposed Lab QA Program and requests public comment on the ICR (prior to submitting the ICR to the Office of Management and Budget (OMB)) is attached in Appendix A.

3(c) Consultations

EPA conducted meetings with representatives of the drinking water treatment industry and the community of laboratories expected to seek EPA recognition under the Laboratory Quality Assurance Evaluation Program in Cincinnati, OH, on January 23 and March 12-13, 2001, and in Washington, DC, on February 13-14, 2001. EPA presented and discussed draft plans for the laboratory evaluation program at these meetings and sought input from the drinking water utility and laboratory representatives that attended these meetings.

3(d) Effects of Less Frequent Collections

Under the Laboratory QA Program, EPA plans on requiring laboratories to analyze single-blind OPT samples three times per year. This frequency is the minimum necessary to enable EPA to independently verify that laboratories continue to perform in an acceptable manner. Less frequent OPT samples would not sufficiently capture a laboratory's performance over time. Laboratories will be required to report OPT results within 15 days of analysis. Reporting OPT sample results at this frequency allows EPA to respond in a timely manner to any problems the laboratory may be having with analysis of *Cryptosporidium* in water.

3(e) General Guidelines

The Laboratory QA Program adheres to all of OMB's general guidelines for information collection.

3(f) Confidentiality

The Laboratory QA Program does not ask any confidential or sensitive questions.

4. The Respondents and the Information Requested

4(a) Respondents/SIC Codes

The following is a list of SIC codes associated with laboratories affected by the requirements of this ICR:

4(b) Information Requested

(i) Data Items

Report on:

- Laboratory participation application information
- Initial performance testing (IPT) data
- Ongoing performance testing (OPT) data
- Documentation of corrective actions taken in response to any deficiencies noted during the on-site evaluation

Maintain:

- IPT data
- OPT data

(ii) Respondent Activities

- Completing laboratory participation application (1 time only)
- Analyzing IPT samples (set of 8 samples, 1 time only per method version) and reporting IPT data
- Analyzing OPT samples (set of 3 samples, 2 time first year only, 3 times per year, per method version) and reporting OPT data
- Hosting on-site evaluation (1 time only)

Note: During the first year that a laboratory participates in the program, the laboratory will analyze one set of IPT samples and two sets of OPT samples. During the second and third years of participation they will analyze three sets of OPT samples.

5. The Information Collected - Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

Agency activities associated with the OGWDW's Laboratory QA Program consist of the following:

- Developing and maintaining a database to review, store, and report on laboratory evaluation data (1 time only)
- Developing and distributing laboratory participation application materials (1 time only)
- Reviewing laboratory participation applications and notifying laboratories of application status (1 time per laboratory)

- Preparing and distributing IPT samples (1 time per laboratory)
- Tracking receipt of and reviewing IPT data (1 time per laboratory)
- Developing checklists for on-site evaluation of laboratories (1 time only)
- Conducting on-site evaluations of the laboratories seeking EPA recognition of laboratory capability and reporting on the results of these on-site evaluations (1 time per laboratory)
- Preparing and distributing OPT samples (2 times first year only, 3 times per year, per laboratory)
- Tracking receipt of and reviewing OPT data and entering the data into a database (2 times first year only, 3 times per year, per laboratory)
- Developing, generating, and distributing reports on laboratory status (3 times per year)

5(b) Collection Methodology and Management

Laboratories interested in obtaining EPA recognition of laboratory capability to perform analyses using EPA Method 1622 and EPA Method 1623 should submit applications to EPA. EPA will evaluate the applications for completeness and compare the information to the recommended criteria specified in the Federal Register Notice (67 FR 9731, March 4, 2002). During on-site evaluations, EPA will evaluate laboratories' performance of the methods, as well as laboratories' data recording and quality control practices using standardized checklists.

IPT and OPT data will be reviewed against the requirements of Method 1622/1623 and the recommended criteria specified in Federal Register Notice (67 FR 9731, March 4, 2002). Data for the IPT and OPT samples will be entered into and stored in a QC database with automated data review and calculation functions. Automating data review functions reduces resources required for data review and ensures that all samples are reviewed in a consistent manner.

5(c) Small Entity Flexibility

The Laboratory QA Program is a voluntary program; any entity that believes this program will impose undue burden is not required to participate in the Laboratory QA Program. Laboratories will still be able to analyze *Cryptosporidium* in water for any purpose where evaluation of laboratory capability is not required.

Small businesses are defined as any business that is independently owned and operated and not dominant in its field as defined by the Small Business Administration (SBA) regulations under Section 3 of the Small Business Act.

Small businesses may opt to seek EPA recognition of laboratory capability to perform *Cryptosporidium* water analyses using only one version of EPA Method 1622 and EPA Method 1623 and reduce the burden associated with participation in the Laboratory QA Program.

5(d) Collection Schedule

The Laboratory QA Program is a voluntary program. No laboratories are required to participate or submit any information.

Any laboratory wishing to participate in the Laboratory QA Program may submit an application for laboratory participation at any time. After the laboratory application has been evaluated by EPA and found to be acceptable, EPA will provide the laboratory with IPT samples. The laboratory will submit IPT sample data to EPA within 15 days of receipt of the IPT samples. After successful completion of the IPT samples, the laboratory will receive a set of OPT samples every four months. Data for these samples will also be submitted within 15 days of receipt of the OPT samples.

6. Estimating the Burden and Cost of the Collection

6(a) Estimating Respondent Burden

Below are summaries of respondent burden hours for this information collection. EPA consulted with fewer than nine respondents from the community of laboratories that may voluntarily apply for EPA recognition of laboratory capability to perform *Cryptosporidium* analyses using EPA Method 1622 and EPA Method 1623 to obtain burden hour estimates. For specific burden breakdowns, refer to the *Laboratories Seeking Approval for One Method* and *Laboratories Seeking Approval for Two Methods* burden tables in Appendix B.

Laboratories may seek EPA recognition of laboratory capability for each version of EPA Method 1622 and EPA Method 1623 that they wish to use for field sample monitoring. Therefore, laboratories seeking EPA recognition of laboratory capability to perform *Cryptosporidium* analyses for one method version incur different burden hours and costs than laboratories seeking EPA recognition for two versions of the method. Hence, there are separate burden tables for laboratories seeking EPA recognition for one method (Table 1, Appendix B) and laboratories seeking EPA recognition for two methods (Table 2, Appendix B). EPA estimates that 40 laboratories will seek EPA recognition for one method and 20 laboratories will seek EPA recognition for two methods.

EPA assumes that not all laboratories that seek EPA recognition will actually be approved due to laboratories failing to meet the criteria of the Lab QA Program specified in the Federal Register Notice (67 FR 9731, March 4, 2002). If a laboratory is not approved, they will not receive OPT samples. For these tasks, EPA estimates that there will be 30 laboratories for one-method approval and 15 laboratories for two-method approval (Appendix B).

Laboratories will submit only one application, regardless of the number of method versions for which they seek EPA recognition. The laboratory participation application requires the following: 1) completing the application form and a self-audit checklist; 2) providing resumes for each staff member seeking EPA recognition under the program; 3) providing copies of existing laboratory procedures for each version of the method for which the laboratory is seeking EPA recognition; and 4) providing the

results of initial demonstration of capability data for each version of the method for which the laboratory is seeking EPA recognition. Since laboratories only have to submit the application one time, the number of laboratories expected to submit applications were evenly distributed over a three year-period to estimate burden hours and costs per year (e.g., laboratories seeking approval for one method, $40 \text{ laboratories} / 3 \text{ years} = \text{approximately } 13 \text{ labs/year}$; laboratories seeking approval for two methods, $20 \text{ laboratories} / 3 \text{ years} = \text{approximately } 7 \text{ laboratories per year}$). Burden hours and costs associated with submitting the completed application package for the laboratories applying for EPA recognition of one method are estimated at 173 labor hours per year. Burden hours associated with submitting the completed application package for the laboratories applying for EPA recognition of two-method versions are estimated at 107 labor hours per year (Appendix B).

Each laboratory will analyze a separate set of IPT samples (8 samples per set) for each version of the method for which they are seeking EPA recognition. The burden for this task includes all labor associated with the actual process of analyzing and documenting the data for each set of IPT samples. Since laboratories only have to analyze a set of IPT samples once, the number of laboratories expected to analyze IPT samples were evenly distributed over a 3-year period to estimate burden hours per year (Appendix B). Burden hours for all laboratories analyzing one set of IPT samples (for one method version) are estimated at 533 labor hours per year. Burden hours for all laboratories analyzing two sets of IPT samples (for two method versions) are estimated at 533 labor hours per year (this represents twice the samples as the one-method laboratories, but almost half the number of laboratories) (Appendix B).

Each laboratory seeking EPA recognition of laboratory capability under the Laboratory QA Program will undergo one on-site evaluation, regardless of the number of methods for which the laboratory seeks EPA recognition. However, this evaluation may require a longer amount of time if the laboratory requests recognition for more than one method version. The burden hours associated with this task include time required to attend short briefings by the auditors before and after the audit, demonstrate the techniques for the methods for which they are seeking EPA recognition, participate in discussions with the auditors, and respond to any deficiencies noted in the audit report. Since laboratories will only undergo an on-site evaluation one time, the number of laboratories expected to be evaluated were evenly distributed over a three year period to estimate burden hours per year (e.g., laboratories seeking approval for one method = $40 \text{ laboratories} / 3 \text{ years} = \text{approximately } 13 \text{ labs/year}$; laboratories seeking approval for two methods = $20 \text{ laboratories} / 3 \text{ years} = \text{approximately } 7 \text{ laboratories per year}$). Burden hours associated with the on-site evaluation for all laboratories applying for EPA recognition of one method version are estimated at 333 labor hours per year. Burden hours for all laboratories applying for laboratory capability recognition of two method versions are estimated at 207 labor hours per year (Appendix B).

Laboratories approved to participate in the program will analyze a set of OPT samples (3 samples per set) every four months for each method for which they are seeking EPA recognition. The burden estimates associated with this task include all labor associated with the actual process of analyzing and documenting the data for each set of OPT samples. During the first year of participation

in the Laboratory QA Program, laboratories will analyze two sets of OPT samples (plus one set of IPT samples) for each method version. During the second and third years of participation laboratories will analyze three sets of OPT samples (no IPT samples). The burden hours and costs in the burden tables (Appendix B) are listed separately for the first year and for the second and third years. Burden hours for all laboratories analyzing one set of OPT samples every four months (for one method version) are estimated at 1230 labor hours per year. Burden hours and costs for all laboratories using two method versions (which require two sets of OPT samples every four months) are estimated at 1230 labor hours (this represents twice the samples as the one-method laboratories, but almost half the number of laboratories).

6(b) Estimating Respondent Costs

Below are summaries of the costs for this information collection. EPA consulted with fewer than nine respondents from the community of laboratories that may voluntarily apply for EPA recognition of laboratory capability to perform *Cryptosporidium* analyses using EPA Method 1622 and EPA Method 1623 to obtain labor and operations and maintenance (O&M) cost estimates, which include overhead costs. For specific cost breakdowns, refer to the *Laboratories Seeking Approval for One Method* and *Laboratories Seeking Approval for Two Methods* tables in Appendix B.

It is assumed that the laboratories wishing to participate in this program are already performing one or two versions of either EPA Method 1622 and EPA Method 1623 for the analysis of *Cryptosporidium* and already have the necessary equipment to perform the analysis, therefore no capital or startup costs were included in the cost estimates. For each task total costs were based on the combined labor and O&M costs for that task.

Cryptosporidium analyses for one method version incur different costs than laboratories seeking EPA recognition for two versions of the method. Hence, there are separate tables for laboratories seeking EPA recognition for one method and laboratories seeking EPA recognition for two methods. EPA estimates that 40 laboratories will seek EPA recognition for one method and 20 laboratories will seek EPA recognition for two methods.

Respondent costs associated with submitting the completed application package for the laboratories applying for EPA recognition of one method is \$5,760 per year (13 respondents/year). Costs associated with submitting the completed application package for the laboratories applying for EPA recognition of two-method is estimated cost of \$3,820 per year (7 respondents/year) (Appendix B).

Respondent costs associated with analysis of IPT samples (total of 8 samples) includes labor and O&M costs, which are estimated at \$303 per analytical sample. Since laboratories only have to analyze a set of IPT samples once per method version, the number of laboratories expected to analyze IPT samples were evenly distributed over a 3-year period to estimate burden hours and costs per year (e.g., laboratories seeking approval for one method, 40 laboratories/3 years = approximately 13

labs/year; laboratories seeking approval for two methods, 20 laboratories/3 years = approximately 7 laboratories per year). Costs for all laboratories (40 laboratories) analyzing one set of IPT samples (for one method version) (labor cost + O&M cost = \$ 2,420) are estimated at \$32,267 per year. Costs for all laboratories (20 laboratories) analyzing two sets of IPT samples (for two method versions) (labor cost + O&M cost = \$4,840) are estimated to be \$32,267 per year (this represents twice the samples as the one-method laboratories, but almost half the number of laboratories).

The costs associated with the on-site evaluation for all laboratories applying for EPA recognition of one method version (approximately 13 laboratories per year) are estimated at \$10,067 per year. The costs for all laboratories applying for laboratory capability recognition of two method versions (approximately 7 laboratories per year) are estimated at \$6,400 per year.

Cost estimates associated with the analysis of OPT samples every four months includes all labor and analytical costs associated with the actual process of analyzing and documenting the data for each set of OPT samples. Labor and costs are estimated at \$303 per analytical sample. Costs for all laboratories analyzing one set of OPT samples every four months (for one method version) are estimated \$72,600 per year. Costs for all laboratories using two method versions (which require two sets of OPT samples every four months) are estimated at \$72,600 per year (this represents twice the samples as the one-method laboratories, but almost half the number of laboratories).

6(c) Estimating Agency Burden and Costs

Below are Agency burden hours and associated financial costs pertaining to implementation of the Laboratory QA Program. For a specific breakdown of burden hours and financial costs, refer to the *Agency Burden* table in Appendix C. Costs and burden hours are broken out based on activities completed by the Agency and supporting contractors. Based on the 2001 GS schedule for the Washington DC/Baltimore area and the standard government benefits multiplication factor of 1.6, EPA estimates an average hourly cost of \$67.36/hour for Agency legal staff, \$57.25/hour for Agency management staff, \$34.00/hour for Agency technical staff, and \$14.77/hour for Agency clerical staff. Based on the published schedule of contractor labor rates for the years covered by this program, the average loaded burden hours and costs for contractor labor were estimated at \$132.50/hour for expert staff, \$69.08/hour for management staff, \$58.32/hour for technical staff, and \$23.44/hour for intern staff.]

Agency burden is estimated based on the labor hours associated with performing each task per laboratory seeking laboratory capability recognition. Hours and costs are then multiplied by the estimated number of respondents and added to the capital and O&M costs. The burden associated with each information collection task is shown in a separate row of the burden table. It is estimated that 60 laboratories (approximately 20 laboratories per year) will seek EPA recognition under the Laboratory Quality Assurance Evaluation Program. Three of the tasks (development and maintenance of a QC database, development of application materials, and development of on-site evaluation checklists), are not affected by the number of laboratories seeking EPA recognition because these costs

and labor hours will be incurred independent of the number of laboratories participating in the program.

To facilitate data storage and data review, the Agency will develop and maintain a QC database. To reduce the burden hours and costs associated with database development, the database will be developed by modifying an existing *Cryptosporidium* results database that serves a similar function. The costs of developing the database are amortized over three years to estimate the burden hours and costs per year. The Agency burden associated with development of the QC database is estimated at 123 labor hours and a total Agency cost of \$7,370 per year.

The Agency will develop application materials, which will include an explanation of the approval process, a list of required materials for the participation application, and an application form, to ensure that the laboratory understands what to submit. Since the application materials will only need to be developed once, the labor hours and costs were distributed over three years to estimate the labor hours and costs per year. The Agency burden associated with development of application materials is estimated at 16 labor hours per year and a cost of \$950 per year.

The Agency will review the laboratory participation applications to ensure that all the required information has been submitted and that each laboratory applicant has the necessary experience and qualifications to acceptably analyze water samples for *Cryptosporidium*. The labor hours and costs associated with this task include reviewing the laboratory application and notifying the laboratory if their application is acceptable or requires submission of additional information. Since each laboratory will only be required to submit an application one time, the number of laboratories expected to seek EPA recognition is evenly distributed over three years in order to determine labor hours and costs per year. The Agency burden associated with review of laboratory participation applications is estimated at 110 labor hours and a cost of \$6,601 per year.

To test the ability of the laboratory to acceptably analyze water samples for *Cryptosporidium*, the Agency will distribute IPT and OPT samples to the laboratories participating in the Laboratory Quality Assurance Evaluation Program. The labor hours and costs associated with this task include notifying laboratories when they will receive their next samples, preparing the samples, and shipping the samples to the laboratories. All the capital startup costs associated with preparing the performance testing samples are included in the costs of preparing the IPT samples. Since each laboratory will only be required to analyze IPT samples once per method version, the number of laboratories expected to analyze IPT samples is evenly distributed over three years in order to determine labor hours and costs per year. The Agency burden associated with preparation of IPT samples is estimated at 80 labor hours per year and a cost of \$6,054 per year. The Agency burden associated with preparation of the OPT samples is estimated at 540 labor hours per year, and a total Agency cost of \$64,187 per year.

The Agency will develop checklist to be used for the on-site evaluation of laboratories to ensure that laboratory evaluations were comprehensive and consistent. Since the checklists only need to be developed once, the labor hours and costs were divided by three years to estimate the labor hours and costs per year. The Agency burden associated with development of checklist for on-site

evaluations is based on 24 labor hours and a total Agency burden of \$1,437 per year.

The Agency will perform on-site evaluations of each laboratory to determine if the laboratory has the required equipment and facilities, has an appropriate QC program in place, and is performing the method properly. Labor hours and costs include scheduling the on-site evaluation, travel, conducting the evaluation, documenting the results of the evaluation, notifying the laboratory of the results of their evaluation, and tracking the progress and costs of these activities. The Agency burden associated with performing on-site evaluations is estimated at 2274 labor hours per year and a cost of \$236,718 per year.

The Agency will review the IPT data submitted by the laboratory to verify that the data submission is complete, the method requirements were met, and that the laboratory's performance was acceptable. After the review is complete, the Agency will notify the laboratory whether their performance on the IPT samples was acceptable. The Agency burden associated with reviewing IPT data is estimated at 100 labor hours per year and a cost of \$6,126 per year.

On an ongoing basis, the Agency will review OPT data submitted by the laboratories to verify that the data submission is complete, the method requirements were met, and that the laboratories' performance was acceptable. The labor hours and costs associated with reviewing these data include data entry into the QC database, automated data review, and notification of the laboratory regarding the results. The Agency burden associated with reviewing OPT data is based on an estimated 270 labor hours per year and a cost of \$16,639 per year.

The Agency will prepare and distribute at least three times per year an updated report on the status of the laboratories that will be participating in the Laboratory QA Program. The labor hours and costs associated with these reports include generation of the reports and posting of laboratory status on an EPA website. The Agency burden associated with the status reports is based on and estimated 12 hours per year and a cost of \$714 per year.

6(d) Estimating the Respondent Universe and Total Burden and Costs

The affected entities include public and private water testing laboratories. EPA estimates that 60 laboratories (approximately 20 laboratories per year) will seek EPA recognition under the Laboratory QA Program and that approximately 45 of these laboratories will be approved. The respondent total burden and cost are provided in the *Total Respondent and Agency Burden Tables* in Appendix D and are described in greater detail in Sections 6(a) - 6(c).

6(e) Bottom Line Burden Hours and Cost Tables

(i) Respondent Tally

Refer to the burden table in Appendix D titled, *Total Respondent and Agency Burden Tables*,

for a specific breakdown of the respondent costs. The Laboratory QA Program will affect approximately 60 respondents (20 laboratories per year). The respondents will engage in 4 different tasks (refer to Section 4(b)(ii)) involving 4347 labor hours and costing approximately \$113,600 per year for labor. Respondents will invest \$0.00 per year in capital/start-up costs and \$123,380 per year in O&M costs.

(ii) Agency Tally

Refer to the burden table in Appendix D titled, *Total Agency and Agency Burden Tables*, for a summary of Agency costs. Nine Agency tasks are associated with the Laboratory QA Program. These tasks will involve approximately 3399 labor hours annually resulting in a cost of \$258,689 per year for labor. The Agency will invest approximately \$16,900 per year in capital/start-up costs and \$71,210 per year in O&M costs.

6(f) Reasons for Change in Burden

Not applicable

6(g) Burden Statement

The reporting and record-keeping burden for this collection is estimated to average 72 hours annually per laboratory (the combined total hours per year for one and two method laboratories divided by 60 laboratories).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Office of Information Collection, Office of Environmental Information, Collection Strategies Division, U. S. Environmental Protection Agency (2822T), 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460-0001; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for EPA. Include the EPA ICR number and OMB

control number in any correspondence.

APPENDIX A

Federal Register Notice:
Laboratory Quality Assurance Evaluation Program/
Information Collection Request

APPENDIX B

Laboratories Seeking Approval for One Method and
Laboratories Seeking Approval for Two Methods Burden Tables

APPENDIX C

Agency Burden Tables

APPENDIX D

Total Respondent and Agency Burden Tables